IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	Lawrence A. Shimp et al.
SERIAL NO.	:	Not Assigned
FILED	:	Concurrently Herewith
FOR	:	SPINAL INTERVERTEBRAL IMPLANT, INTERCONNECTIONS FOR SUCH IMPLANT AND PROCESSES FOR MAKING
EXAMINER	:	Not assigned ART UNIT: Not Assigned
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PRELIMINARY AMENDMENT

Box Patent Application
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Sir:

This paper is a preliminary amendment accompanying a patent application for Letters Patent.

IN THE CLAIMS

Amend the claims as follows:

72 (Amended). An implant comprising:

a first planar member having two opposing broad surfaces having a periphery defining a first plurality of edges;

a second L-shaped member having a first base member defined by a

second plurality of edges and a first leg extending from the base member at one base member edge forming a first recess, the first member being disposed in the first recess with an edge of the first member abutting the first leg, the edges of the first base member and the edges of the first member being coextensive; and

means for securing the first member to the second member.

73 (Amended). The implant of claim 72 wherein the abutment of the first member with the second member leg preclude translation of the first member in a direction toward the leg, the means for securing including a pin in the first and second members under tension and compression to provide a relative compressive load between the first and second members in a direction to force the first member toward said leg.

74 (Amended). The implant of claim 72 wherein the first member is L-shaped including a second leg and a second base member which forms a second recess, the first and second base members overlying each other with the first leg overlying an edge of the second base member and the second leg overlying an edge of the first base member.

75 (Amended). An implant comprising:

a first L-shaped member having a first base portion and a first leg portion;

a second L-shaped member having a second base portion and second leg portion;

a third planar member disposed between the first and second base portions and between the first and second leg portions;

and means for securing the members together.

76 (Amended). The implant of claim 75 wherein the means for securing comprises a pin in interference fit with a corresponding bore in at least the first and second members.

77 (Amended). The implant of claim 76 wherein the bores of the first and second members and the pin are arranged to place the pin in both compression and tension to provide a compressive load on the first and second members.

78 (Amended). The implant of claim 76 wherein the first and second members are cortical bone.

79 (Amended). A spinal implant comprising:

a stacked plurality of planar cortical bone sheets each with a bore, the

implant having a length dimension in a given direction, the sheets each having an abutting interface surface extending in the length direction with the corresponding bore at said interface; and

means including a pin extending transversely the length direction in said bores for securing the sheets together, the bores and pin being arranged so that the pin exhibits compressive and tensile forces for applying a compressive load on at least two of said sheets to hold the sheets together.

80 (Amended). A spinal implant comprising:

a stacked plurality of planar cortical bone sheets, the implant having a length dimension in a given direction, the sheets each having an interface surface abutting an adjacent sheet extending transversely the length direction and a bore at the interface surface; and

a cortical bone pin extending in the length direction in said bores for securing the sheets together.

81 (Amended). The implant of claim 80 wherein the bores and pin are arranged so that the pin exhibits compressive and tensile forces for applying a compressive load on at least two of the sheets.

82 (Amended). A spinal implant comprising:

a member of formed of cortical bone, the member having an anterior end defined by an anterior end surface and a posterior end defined by a posterior end surface, the implant having first and second side surfaces terminating at said end surfaces, the side surfaces comprising mirror image continuous curved surfaces.

83 (Amended). The implant of claim 82 wherein the curved surfaces are convex.

84 (Amended). The implant of claim 82 wherein the member has first and second opposing surfaces that are inclined relative to each other terminating at said end surfaces so that the anterior end is greater in height between the opposing surfaces than the posterior end,

85 (Amended). The implant of claim 83 wherein the curved surfaces are each defined by at least one radius.

86 (Amended). A cortical bone implant member comprising:

a cortical bone plank defined by opposing sides each having a surface, the plank being surrounded by a peripheral edge, the plank having a fiber direction generally parallel to the opposing side surfaces, the plank have a length

dimension and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the plank having at least one through bore in communication with said sides.

87. A bone implant comprising:

first and second cortical bone planks each defined by opposing sides each side having a surface and surrounded by a peripheral edge, the planks having a fiber direction generally parallel to the opposing side surfaces, each plank having a length dimension defining a longitudinal direction and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the planks each having at least one through bore in communication with said side surfaces; and

a cortical bone pin in interference fit with each said bores wherein the pin applies a compressive load on the corresponding planks in opposing longitudinal directions.

88 (Amended). A method of forming a bone implant comprising:

assembling two cortical bone planks in parallel abutting relation;

boring at least one first bore in one of the bone planks in a first direction; and

boring at least one second bore in the other of the bone planks in a second direction generally opposite the first direction wherein the first and second bores are offset relative to each an amount such that a straight bone pin inserted in the bores is placed in compression and tension.

89 (Amended). The method of claim 88 wherein the bores have parallel axes.

90 (Amended). The method of claim 88 wherein the offset of the axes is in the range of about 0.1-10 mm.

91 (Amended). The method of claim 90 wherein the offset comprises forming the first bore with its axis at an angle to the axis of the second bore.

92 (Amended). The method of claim 90 wherein the first and second bores are at a first angle relative to the planks, further including boring third bore in the first plank and a boring a fourth bore in the second plank at a second angle different than the first angle.

93 (Amended). The method of claim 92 wherein the planks have an interface defining a plane, the method including boring the first and second bores at a first

angle that is non-perpendicular with respect to the plane of the planks.

94 (Amended). The method of claim 93 wherein the third and fourth bores are bored at a second angle that is non-perpendicular with respect to the plane of the planks but in mirror image relation to the first and second bores.

95 (Amended). The method of claim 93 wherein the third and fourth bores are bored at a second angle normal to the plane of the planks.

96. A method of forming an implant comprising:

forming first and second cortical bone planks;

forming a bore in each said planks; and

inserting a bone pin in the bores so as to cause the pin to exhibit both compressive and tensile loads which compressively secure the planks to the pin.

97 (Amended). The method of claim 96 including forming the pin from cortical bone exhibiting a fiber direction, the pin having a length dimension, the fiber extending in the length direction.

98 (Amended). The method of claim 96 including surface demineralizing the

bores.

99 (Amended). The method of claim 96 including demineralizing at least the surface of said pin.

100 (Amended). The method of claim 96 including surface demineralize said bores and said pin.

101 (Amended). The method of claim 96 including fully demineralizing at least a portion of the pin and surface demineralilzing the implant and said bores.

102 (Amended). A method of forming a bone implant comprising:

clamping a bone between first and second clamp members such that an end portion of the bone overhangs an end of the clamp members; and

removing a portion of the overhanging end portion of the bone to form an implant plank.

103 (Amended). A method of forming an implant comprising:

forming a plurality of implant members each defining a plane;

abutting the members; and

attaching a pin to the abutting members transverse to the plane and creating opposing compressive forces against the members by creating compressive and tensile bending loads in the pin to resist forces which otherwise tend to separate the members.

104 (Amended). The method of claim 103 including forming the implant members of cortical bone.

105 (Amended). The method of claim 103 including forming the pin of cortical bone.

106 (Amended). The method of claim 103 wherein the step of attaching includes bending the pin during the insertion of the pin into bores in the members.

107 (Amended). The method of claim 103 wherein the step of forming the implant members includes the step of forming the implant members with first and second offset bores and the step of attaching includes forming a straight cylindrical pin and forcing the pin into the offset bores to bend the pin.

108 (Amended). The method of claim 103 wherein the step of forming the implant

members includes forming first and second aligned bores of substantially the same transverse dimension in each member and the step of attaching the pin includes forming the pin with offset sections and then inserting the offset sections into said bores to bend the pin.

109 (Amended). The method of claim 103 wherein the implant has load bearing surfaces, the members comprising fibrous bone having a given fiber direction, further including forming the implant with the bone fiber direction normal to the load bearing surfaces.

110 (Amended). A method of forming an implant comprising:

forming first and second cortical bone members with a bore in each member;

contracting a cortical bone pin by dehydrating the pin;

inserting the dehydrated pin in the bore of each member; and then

expanding the inserted pin to create an interference fit between the pin and bone members in the bores.

111 (Amended). The method of claim 110 wherein the expanding step comprises immersing the inserted pin and attached bone members in a fluid solution.

112 (Amended). The method of claim 110 wherein the dehydrating contracting step includes placing the pin in a vacuum.

113 (Amended). The method of claim 110 wherein the expanding step includes hydrating the pin.

114 (Amended). A spinal implant comprising:

first and second cortical bone planks each having fibers oriented in a direction parallel to a vertebral load thereon and normal to an insertion direction into the disc space between adjacent vertebra;

each plank having a demineralized load bearing surface for abutting an adjacent vertebra; and

means for securing the planks to each other with the demineralized surfaces coextensive.

REMARKS

This amendment accompanies a new application for Letters Patent. The claims 73-115 of the application are misnumbered. There is no claim 72 and there is a duplicate claim 115. This amendment corrects the claim numbering of claims 73-115 (first occurrence) to 72-114. Present claims 1-72 and 115 (second

occurrence)-138 remain unchanged.

Enclosed is a copy of the changed version of the claims.

Entry of this amendment is respectfully requested.

Respectfully submitted,
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VERSION SHOWING CHANGES TO CLAIMS

72
~~73~~. An implant comprising:

a first planar member having two opposing broad surfaces having a periphery defining a first plurality of edges;

a second L-shaped member having a first base member defined by a second plurality of edges and a first leg extending from the base member at one base member edge forming a first recess, the first member being disposed in the first recess with an edge of the first member abutting the first leg, the edges of the first base member and the edges of the first member being coextensive; and

means for securing the first member to the second member.

73 72
~~74~~. The implant of claim ~~73~~ wherein the abutment of the first member with the second member leg preclude translation of the first member in a direction toward the leg, the means for securing including a pin in the first and second members under tension and compression to provide a relative compressive load between the first and second members in a direction to force the first member toward said leg.

74 72
~~75~~. The implant of claim ~~73~~ wherein the first member is L-shaped including a second leg and a second base member which forms a second recess, the first

and second base members overlying each other with the first leg overlying an edge of the second base member and the second leg overlying an edge of the first base member.

75
~~76~~. An implant comprising:

a first L-shaped member having a first base portion and a first leg portion;

a second L-shaped member having a second base portion and second leg portion;

a third planar member disposed between the first and second base portions and between the first and second leg portions;

and means for securing the members together.

76 75
~~77~~. The implant of claim ~~76~~ wherein the means for securing comprises a pin in interference fit with a corresponding bore in at least the first and second members.

77 76
~~78~~. The implant of claim ~~77~~ wherein the bores of the first and second members and the pin are arranged to place the pin in both compression and tension to provide a compressive load on the first and second members.

78 76
~~79~~. The implant of claim ~~77~~ wherein the first and second members are cortical bone.

79

~~80~~. A spinal implant comprising:

a stacked plurality of planar cortical bone sheets each with a bore, the implant having a length dimension in a given direction, the sheets each having an abutting interface surface extending in the length direction with the corresponding bore at said interface; and

means including a pin extending transversely the length direction in said bores for securing the sheets together, the bores and pin being arranged so that the pin exhibits compressive and tensile forces for applying a compressive load on at least two of said sheets to hold the sheets together.

80

~~81~~. A spinal implant comprising:

a stacked plurality of planar cortical bone sheets, the implant having a length dimension in a given direction, the sheets each having an interface surface abutting an adjacent sheet extending transversely the length direction and a bore at the interface surface; and

a cortical bone pin extending in the length direction in said bores for securing the sheets together.

81 80

~~82~~. The implant of claim ~~81~~ wherein the bores and pin are arranged so that the

pin exhibits compressive and tensile forces for applying a compressive load on at least two of the sheets.

82
~~83~~. A spinal implant comprising:

a member of formed of cortical bone, the member having an anterior end defined by an anterior end surface and a posterior end defined by a posterior end surface, the implant having first and second side surfaces terminating at said end surfaces, the side surfaces comprising mirror image continuous curved surfaces.

83 82
~~84~~. The implant of claim ~~83~~ wherein the curved surfaces are convex.

84 82
~~85~~. The implant of claim ~~83~~ wherein the member has first and second opposing surfaces that are inclined relative to each other terminating at said end surfaces so that the anterior end is greater in height between the opposing surfaces than the posterior end,

85 83
~~86~~. The implant of claim ~~84~~ wherein the curved surfaces are each defined by at least one radius.

86

~~87~~. A cortical bone implant member comprising:

a cortical bone plank defined by opposing sides each having a surface, the plank being surrounded by a peripheral edge, the plank having a fiber direction generally parallel to the opposing side surfaces, the plank have a length dimension and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the plank having at least one through bore in communication with said sides.

87

~~88~~. A bone implant comprising:

first and second cortical bone planks each defined by opposing sides each side having a surface and surrounded by a peripheral edge, the planks having a fiber direction generally parallel to the opposing side surfaces, each plank having a length dimension defining a longitudinal direction and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the planks each having at least one through bore in communication with said side surfaces; and

a cortical bone pin in interference fit with each said bores wherein the pin applies a compressive load on the corresponding planks in opposing longitudinal directions.

88.
~~89~~. A method of forming a bone implant comprising:

assembling two cortical bone planks in parallel abutting relation;

boring at least one first bore in one of the bone planks in a first direction; and

boring at least one second bore in the other of the bone planks in a second direction generally opposite the first direction wherein the first and second bores are offset relative to each an amount such that a straight bone pin inserted in the bores is placed in compression and tension.

89. 88
~~90~~. The method of claim ~~89~~ wherein the bores have parallel axes.

90 88
~~91~~, The method of claim ~~89~~ wherein the offset of the axes is in the range of about 0.1-10 mm.

91 90
~~92~~. The method of claim ~~91~~ wherein the offset comprises forming the first bore with its axis at an angle to the axis of the second bore.

92 90
~~93~~. The method of claim ~~91~~ wherein the first and second bores are at a first angle relative to the planks, further including boring third bore in the first plank and a

boring a fourth bore in the second plank at a second angle different than the first angle.

93 92
~~94~~. The method of claim ~~93~~ wherein the planks have an interface defining a plane, the method including boring the first and second bores at a first angle that is non-perpendicular with respect to the plane of the planks.

94 93
~~95~~. The method of claim ~~94~~ wherein the third and fourth bores are bored at a second angle that is non-perpendicular with respect to the plane of the planks but in mirror image relation to the first and second bores.

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96
~~97~~. A method of forming an implant comprising:

forming first and second cortical bone planks;

forming a bore in each said planks; and

inserting a bone pin in the bores so as to cause the pin to exhibit both compressive and tensile loads which compressively secure the planks to the pin.

97 96
~~98~~. The method of claim ~~97~~ including forming the pin from cortical bone exhibiting a fiber direction, the pin having a length dimension, the fiber extending in the length direction.

98 96
~~99~~. The method of claim ~~97~~ including surface demineralizing the bores.

99 96
~~100~~. The method of claim ~~97~~ including demineralizing at least the surface of said pin.

100 96
~~101~~. The method of claim ~~97~~ including surface demineralize said bores and said pin.

101 96
~~102~~. The method of claim ~~97~~ including fully demineralizing at least a portion of the pin and surface demineralilzing the implant and said bores.

102
~~103~~. A method of forming a bone implant comprising:

clamping a bone between first and second clamp members such that an end portion of the bone overhangs an end of the clamp members; and

removing a portion of the overhanging end portion of the bone to form an

implant plank.

103
~~104~~. A method of forming an implant comprising:

forming a plurality of implant members each defining a plane;

abutting the members; and

attaching a pin to the abutting members transverse to the plane and creating opposing compressive forces against the members by creating compressive and tensile bending loads in the pin to resist forces which otherwise tend to separate the members.

104 103
~~105~~. The method of claim ~~104~~ including forming the implant members of cortical bone.

105 103
~~106~~. The method of claim ~~104~~ including forming the pin of cortical bone.

106 103
~~107~~. The method of claim ~~104~~ wherein the step of attaching includes bending the pin during the insertion of the pin into bores in the members.

107 103
~~108~~. The method of claim ~~104~~ wherein the step of forming the implant members includes the step of forming the implant members with first and second offset bores and the step of attaching includes forming a straight cylindrical pin and

forcing the pin into the offset bores to bend the pin.

108 103
~~109~~. The method of claim ~~104~~ wherein the step of forming the implant members includes forming first and second aligned bores of substantially the same transverse dimension in each member and the step of attaching the pin includes forming the pin with offset sections and then inserting the offset sections into said bores to bend the pin.

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~~110~~. The method of claim ~~104~~ wherein the implant has load bearing surfaces, the members comprising fibrous bone having a given fiber direction, further including forming the implant with the bone fiber direction normal to the load bearing surfaces.

110
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forming first and second cortical bone members with a bore in each member;

contracting a cortical bone pin by dehydrating the pin;

inserting the dehydrated pin in the bore of each member; and then

expanding the inserted pin to create an interference fit between the pin and bone members in the bores.

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~~112~~. The method of claim ~~111~~ wherein the expanding step comprises immersing the inserted pin and attached bone members in a fluid solution.

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~~115~~. A spinal implant comprising:

first and second cortical bone planks each having fibers oriented in a direction parallel to a vertebral load thereon and normal to an insertion direction into the disc space between adjacent vertebra;

each plank having a demineralized load bearing surface for abutting an adjacent vertebra; and

means for securing the planks to each other with the demineralized surfaces coextensive.